REMARKS

As an initial matter, Applicant appreciates the thorough examination and comments provided by the Examiner.

The Examiner's Rejections

The Examiner rejects claims 1-3 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,478,479 to Herrig in view of U.S. Patent No. 5,431,620 to Schenck, U.S. Patent No. 4,086,924 to Latham, and U.S. Patent No. 5,242,384 to Robinson.

The Examiner also rejects claims 4-7 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2003/0158513 to Brannon et al. in view of Herrig, Schenck, Latham, and Robinson.

In response to the Examiner's rejections, Applicant submits amended claims and addresses the Examiner's concerns herein below.

Amended Independent Claim 1 is Not Obvious

The Examiner rejects, among others, independent claim 1 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,478,479 to Herrig in view of U.S. Patent No. 5,431,620 to Schenck, U.S. Patent No. 4,086,924 to Latham, and U.S. Patent No. 5,242,384 to Robinson. Applicant disagrees with the Examiner's assessment of the structure and function of Herrig for the reasons set forth below.

Herrig

U.S. Patent No. 5,478,479 to Herrig discloses a system and method of washing salvaged blood that incorporates a variety of lines 26, 21, 30, 32 for transporting blood in communication with a wound 12a, a source 19 for suctioning blood, a salvaged blood reservoir 16, a collection bag 24 for collecting treated blood, and a pump P operating to transport blood between the reservoir 16 and centrifuge bowl 20 and the collection bag 24. Critical to its functioning, Herring further provides an optical line sensor 7 connected to the salvaged blood reservoir and controlling the speed of the pump, the number of wash stages, and the volume of wash solution employed for washing blood components.

Specifically, Herrig discloses a suction line 26 restricted to suctioning blood lost from the wound 12a of the patient 12. Once the blood is treated by the centrifuge bowl 20 and wash solution 18, the blood is collected in the collection bag 24. Thereafter, the treated blood is transferred via line 38 (a line different from suction line 26) to a secondary bag (not shown) for reinfusion into the patient via a separate line and separate phlebotomy needle (i.e., a line and device separate from the suction line 26 and collection needle at the wound).

Herring teaches the transport of blood from a patient to a centrifuge and then to a bag via lines—Herrig fails to teach a device having a single external unit for withdrawing fat and subsequently injecting treated fat, wherein the external unit includes a vessel that is removed from the external unit once fat is collected, transferred to a centrifuge for treatment, and subsequently returned to the external unit for injection into a patient.

The Examiner argues that Herrig teaches "an integrated system for withdrawing body tissue (blood, which includes blood cells) from the body, centrifuging the tissue, and then returning parts of the withdrawn tissue to the patient." Office Action, page 2, paragraph 2. The Examiner then alleges that "conceptually, this is the same as the instant invention." *Id.* (emphasis added). Applicant submits that "conception" requires a

reduction to practice, and that reduction to practice may result in any number of patentably distinct systems and methods—as in the present case.

In contrast to Herrig, the present invention as described in amended claim 1 incorporates a single external unit (i.e., hand-held unit) for suctioning and injecting fat, wherein the external unit includes a cannula and vessel for collecting, retaining, and delivering fat via the same external unit.

Herrig neither discloses nor teaches a system for performing liposuction or lipoinjection, wherein a single external unit having a vessel and a cannula is used to collect, retain, and deliver fat once the vessel is centrifuged.

Schenck

U.S. Patent No. 5,431,620 to Schenck discloses a centrifuge system and method for measuring and then adjusting various process parameters of a centrifugal operation (i.e., windage, temperature, and moment of inertia). Referring to Figure 1, the system includes a centrifuge 10 having a housing 32, a hub 26 connecting a rotor 16 to a drive shaft 14 and motor 12, and a vacuum pump 36 in communication with the interior atmosphere of the housing (i.e., centrifuge chamber). The vacuum pump communicates with the interior of the housing via a first annular gap 54, a second annular gap 56, and a conduit 38 to thereby create a vacuum (or near vacuum) in the centrifuge chamber. The rotor includes containers 18 and 20 for receiving samples.

In operation, the vacuum pump evacuates air from the centrifuge chamber upwardly into the second annular gap 56 and then downwardly into the first annular gap 54, whereafter evacuated air is channeled to the vacuum pump 36.

In particular, the system and method measures one or more physical characteristics of a rotor to accomplish the following:

(1) determine windage (i.e., power consumed in pumping the gaseous atmosphere surrounding the rotor) and thereafter adjust a vacuum system based upon changes in the rotational speed of the rotor;

(2) determine windage and thereafter adjust temperature within the compartment by way of a refrigeration circuit and coils; and

(3) determine windage and thereafter adjust adaptive circuitry of the centrifuge drive system.

See Abstract; Col. 4, lines 32-38; Col. 4, line 67 to Col. 5, lines 1-2; and Col. 5, lines 61-62.

Thus, Schenk requires a housing in communication with a vacuum pump by way of first and second annular gaps such that the atmosphere within the enclosed chamber may be controlled and a proper environment may be maintained such that the invention can measure one or more physical characteristics of the rotor such as windage and moment of inertia. The purpose of Schenck is to adjust the parameters of centrifuge operation based upon windage.

Accordingly, Schenck discloses a centrifuge for optimizing centrifugal operations by measuring windage and then adjusting air pressure and temperature within the chamber as well as adjusting circuitry operating the centrifuge drive system.

Schenck fails to disclose a centrifuge having an external unit for performing liposuction and lipoinjection, wherein the external unit is a fat injection vessel. As configured, the sole function of Schenck is centrifugation and the optimization of that operation by forming a vacuum within the centrifuge chamber.

Herrig Fails to Disclose an External Unit for Both Collecting Fat and Injecting Treated Fat

In contrast to Herrig, the present invention provides a system and method for performing liposuction, centrifugation, and lipoinjection wherein the system incorporates a manually-operated external unit 22 (i.e., cannula and vessel) for collecting fat from a patient and thereafter delivering by way of injection centrifuged fat via a single unit 22. Stated differently, the present invention relies upon a single external unit to suction fat from a patient and deliver centrifuged fat into the patient.

As configured, the present invention incorporates a fat injection vessel or external unit 22 having a syringe and cannula such that a user can perform liposuction, obtain filtered fat by centrifugation of the vessel once removed from the external unit, and thereafter perform lipoinjection once the vessel is returned to the external unit, wherein the operation relies upon a single instrument.

Herrig fails to disclose a sole external unit for collecting, retaining, and injecting fat, therefore, even if combined the cited references would not produce the claimed invention.

Herrig Fails to Disclose a Pump Device that Functions to Suction Fat and Thereafter Inject Treated Fat

Herrig fails to disclose a pump device for selectively performing vacuum or compression to withdraw or thereafter inject blood, respectively. The Examiner argues that the phrase "into and out of centrifuge bowl" suggests vacuum/blood-draw or compression/blood-injection as felt by the patient. Office Action, page 5. More accurately, Herrig discloses a separate source 19 that provides a vacuum within suction line 26 such that the suction line 26 draws blood from the wound 12a into a reservoir 16. Fig. 1; and Column 2, line 67 to column 3, line 2. The vacuum source 19 is separate and apart from the pump P. Thus, the vacuum source 19 suctions blood and not the pump P.

As taught by Herrig, the pump P operates on the salvaged blood in the reservoir 16. The action of the pump P does not and is incapable of suctioning blood from the patient's body as claimed in the present invention. In other words, Herrig's pump merely affects the blood traveling through lines 30, 32, and 36.

Thus, Herrig fails to disclose, teach, or even suggest a single external unit having a vessel and cannula for collecting fat and delivering centrifuged fat. Further, Herrig fails to disclose a pump for withdrawing and injecting blood or fat.

The combination of Herrig with the remaining cited references fails to disclose Applicant's invention that performs liposuction, centrifugation, and lipoinjection by providing a single external unit in the form of a cannula and a fat injection vessel, wherein a single pump operates to suction fat (as well as blood) from a patient during liposuction and thereafter inject treated fat during lipoinjection.

Accordingly, Applicant submits that amended claim 1, and claims 2-3 depending therefrom, are not obvious.

The Combination of Herrig with Other References Would be Impractical and Render the Device Inoperative

Contrary to the Examiner's suggestions, combining the centrifuge buckets 18, 20 of Schenck with the centrifuge 20 of Herrig would be impractical as well as inoperative.

Herrig discloses a centrifuge bowl 20 having a separation chamber 76 defined by an outer wall 70 and core 72 of the centrifuge bowl 20, and a radial passageway 74 defined by the bottom 72a of the core 72 and the bottom wall 70a of centrifuge bowl 20. Blood enters the separation chamber 76 of centrifuge bowl 20 (Fig. 2) at the bottom of centrifuge bowl 20 via a feed tube (not shown) and radial passageway 74 at the bottom of the centrifuge.

Schenck discloses a rotor 16 having a chamber for receiving containers 18, 20.

Applicant notes that Herring fails to disclose a centrifuge structure capable of receiving the containers 18 and 20 of Schenck. Specifically, the centrifuge 20 of Herrig does not provide a lid and the only access to the separation chamber is a radial passageway 74.

Thus, the combination of Herrig and Schenk would be impractical, requiring the following actions to combine the two:

- Modifying Herrig to include an opening on an upper part of its centrifuge bowl 20;
- Adding an additional component (i.e., a lid) to Herrig;
- Modifying the separation chamber 76 of Herrig to receive a container 18, 20; and
- Eliminating the radial passageway 74 of Herrig such that it could support a container 18, 20.

Such modifications, deletions, and additions to the structure of Herrig would be impractical, expensive, and render the device inoperative. Specifically, such modification would block lines 30, 32 and 36, and prevent Herrig from monitoring and treating drawn blood because the blood would travel to and from the patient via a vial or vessel. In other words, such a modification would render blood flow lines 30, 32, and 36 inoperable, and eliminate monitoring of the blood level in reservoir 16 by sensor 17.

Moreover the modification would prevent the optical line sensor 7 from controlling the speed of the pump P because blood would travel to and from the centrifuge via a vial, and not lines 30, 32, and 36.

Integration of Parts Not Sufficient for Finding of Obviousness

The Examiner argues that it would have been obvious to modify Herrig with Schenck, Latham, and Robinson for the purpose of integrating the different parts of a

surgical procedure into one unit. Applicant submits the "mere fact that a worker in the art could arrange the parts of a referenced device to meet the terms of claims on appeal is not by itself sufficient to support a finding of obviousness." *Ex Parte Chicago Rawhide Mfg. Co.*, 223 U.S.P.Q. 351, 353 (Bd. Pat. App. & Inter. 1984). The purported rearranging of the elements of the cited references defeats the purpose of Herrig (i.e., withdraw blood with one needle via a vacuum source, treat the blood via a separate pump and centrifuge, monitor blood in the fluid communication lines, and then subsequently reinject the treated blood with a separate needle).

Herring and Schenck Teach Away From Present Invention

The Supreme Court recently addressed the standard for determining obviousness in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007). The Court stated that the *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 86 S.Ct. 648 (1966) factors still control an obviousness inquiry. Those factors are: the scope and content of the prior art; the differences between the prior art and the claims at issue; and the level of ordinary skill in the pertinent art. *Id.*, 127 S.Ct. at 1734 (quoting *Graham*, 383 U.S. at 17-18).

The *KSR* Court recognized that prior art teaching away from combining certain elements is an indicator of the nonobviousness of a claimed invention. *KSR*, 127 S. Ct. at 1740 (citing *United States v. Adams*, 383 U.S. 39, 86 S.Ct. 708 (1966)). *See also In re Sullivan*, 2007 U.S. App. LEXIS 20600 (Fed. Cir. 2007) (Evidence rebutting a prima face case of obviousness of a claimed invention can include evidence that prior art teaches away from the claimed invention in any material respect).

The claimed invention differs significantly from the Herrig system, and the Examiner admits that Herrig does not teach elements of the claimed invention. Further, Herring and the remaining references do not suggest modifying the device in the manner described by the Examiner. Indeed, modifying Herrig with components of the remaining references in the manner proposed by the Examiner would actually frustrate the intended

purpose of Herrig—i.e., the suctioning and transport of blood via lines, treatment of blood in a centrifuge in fluid communication with the lines, monitoring the blood in the lines, and the subsequent delivery of blood back to the patient via a separate bag and needle. Simply stated, Herring teaches the transport of blood to and from a centrifuge via lines. The claimed invention pertains to the transport of blood to and from a centrifuge via a vessel. Thus, Herrig teaches away from the claimed invention. The Supreme Court confirmed in its *KSR* decision that, as in the current application, prior art teaching away from combining certain elements is an indicator of the nonobviousness of a claimed invention.

Amended Independent Claim 4 is Not Obvious

The Examiner also rejects claims 4-7 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2003/0158513 to Brannon et al. in view of Herrig, Schenck, Latham, and Robinson.

Brannon

The Examiner admits that Brannon does not teach the specific features of the claim centrifuge.

Applicant has shown above that Herrig combined with any of the remaining cited references fails to teach the features of the centrifuge.

Herring is an Improper References and Cannot Be Combined with Brannon

The Examiner alleges that it would have been obvious to modify or combine Brannon in combination with Herring, Schenck, Latham, and Robinson for the purpose of streamlining the procedure of liposuction and lipoinjection. Having set forth the structural and functional differences between Herrig and Schenck, and the subject invention, Applicant submits that the cited patents are improper references under §103(a).

Accordingly the Examiner's rejection of claims 4-7 under §103(b) in reliance upon Herring and Schenck is now improper.

Amended Independent Claim 1 is Patentable

Amended independent claim 1 now recites a system having a single manually-operated external unit for performing liposuction and lipoinjection, wherein the external unit 22 includes a vessel for retaining fat, and a cannula for collecting fat and delivering centrifuged fat. Further, amended claim 1 now recites that the pump operates to withdraw fat and inject treated fat via the same external unit 22, and not multiple units (e.g., needles and bags) as set forth in the prior art.

Herrig in combination with the cited references fails to disclose the system described in amended independent claim 1—and in particular fails to disclose an external unit, centrifuge, and pump of the type claimed herein—and therefore must be removed as proper §103(a) references. Accordingly, Applicant submits that amended claim 1 is not obvious and is now allowable.

Amended Independent Claim 4 is Patentable

Amended independent claim 4 now recites a method of performing liposuction, centrifugation, and lipoinjection using a single external unit 22 that a vessel for retaining fat, and a cannula for collecting fat and delivering centrifuged fat. Amended claim 4 now recites that the pump operates to withdraw fat and inject treated fat via the same external unit 22

Brannon in combination with Herring, Schenck, Latham, and Robinson fails to disclose the system described in amended independent claim 1 and therefore must be removed as proper §103(a) references. Accordingly, Applicant submits that amended claim 4 is not obvious and is now allowable.

CONCLUSION

Based on foregoing amendments and arguments, Applicant submits that pending claims 1-7 are now in immediate condition for allowance, and the same is respectfully requested.

Respectfully submitted,

//Jesse B. Ashe, III//

Jesse B. Ashe, III
Registration No. 44,513

021176
Summa, Additon & Ashe, P.A.
11610 North Community House Road
Suite 200
Charlotte, NC 28277-2162
Telephone: 704-945-6703
Facsimile: 704-945-6735
File No.: 1114.005

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